Scientific Abstract for HVTN 061:

The development of a safe and effective prophylactic HIV-1 vaccine is a global health priority. Wyeth Research is pursuing development of a combination HIV vaccine regimen consisting of CTL multiepitope peptides (HIV CTL MEP) and facilitated DNA technology (HIV-1 *gag* DNA + *IL-12* DNA or *IL-15* DNA) platforms. It is anticipated that a combination prime/boost approach will build on the strengths of each technology and provide the desired breadth and robustness of cellular immune responses that are required to confer protective immunity. In HVTN 061, subjects from HVTN Protocol 056 who have received priming with HIV CTL MEP and RC529-SE adjuvant with or without GM-CSF cytokine adjuvant, or who have received placebo, will receive booster vaccinations of HIV CTL MEP/ RC529-SE adjuvant with or without GM-CSF, or of HIV-1 *gag* DNA + human *IL-12* DNA, or of placebo. The multicenter, randomized, placebo-controlled, double blinded study will involve up to 96 HIV-uninfected healthy adult participants. Subjects will receive either the same vaccine they received in Protocol 056, or HIV-1 *gag* DNA + *IL-12* DNA. Placebo recipients in Protocol 056 will again receive placebo in this trial. Blinding of Protocol 056 treatment assignment for Protocol 061 participants will continue until Protocol 061 has concluded.

There is no prior animal experience of the HIV CTL MEP vaccine and the HIV-1 *gag* DNA + *IL-12* DNA vaccine being used sequentially in the same animal. In animal experiments of each of the vaccines given separately, the vaccines with adjuvants were well-tolerated and immunogenic.

The primary objectives of the present study are:

- To evaluate the safety and tolerability of HIV-1 *gag* DNA vaccine given concurrently with *IL-12* DNA adjuvant employed as a boost vaccination following priming with the HIV CTL MEP / RC529-SE vaccine with and without GM-CSF
- To evaluate the safety and tolerability of the HIV CTL MEP / RC529-SE vaccine (with and without GM-CSF) employed as a boost vaccination following priming with the HIV CTL MEP / RC529-SE vaccine, with GM-CSF
- To evaluate the safety and tolerability of the HIV CTL MEP / RC529-SE vaccine (with and without GM-CSF) employed as a boost vaccination following priming with the HIV CTL MEP / RC529-SE vaccine, without GM-CSF